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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,110	12/07/2004	Javier Segado Ferran	OFICINA-250281	1427

54042 7590 06/25/2010

Cozen O'"Connor
277 PARK AVENUE
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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,110	FERRAN, JAVIER SEGADO	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's amendment, remarks, and IDS filed on 11 March 2010.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/12161 ("Martani") in view of S.T.P. Pharma Sciences 11 (3) 211-220, 2001 ("Mattsson") (cited in the IDS filed on 7 December 2004).

Martani teaches a tablet which disintegrates in the oral cavity within 30 seconds (*see* page 9, second full-paragraph) comprising:

- at least 60% mannitol (*see* page 11, third full-paragraph);
- active ingredient below 10% (*see* example 1);
- at least 30% microcrystalline cellulose (*see* page 11, third full-paragraph);
- 1-15% sodium croscarmellose (*see* paragraph bridging pages 11 and 12);
- 0.3-5% lubricant (*see* page 12, first full-paragraph); and
- a density of up to 1g/ml (*see* page 9, second full-paragraph).

Martani does not explicitly teach the claimed particle sizes, friability values, and proportion of insoluble elements, however, it is the position of the Examiner that it would

have been obvious to one of ordinary skill in the art at the time the invention was made to determine these values through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in particle sizes, friability values, and proportion of insoluble elements will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating the claimed values are critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from claimed values. Furthermore, since the prior art tablet demonstrates the same disintegration time as that being claimed, i.e. 30 seconds, and has the same ingredients (most of which are in overlapping or very close proportions), a person of ordinary skill in the art would expect that friability values, proportion of insoluble elements, and particle sizes would be similar between the prior art and the instant application.

Alternatively, Mattsson teaches a rapidly disintegrating tablet formulation comprising microcrystalline cellulose particles of less than 20 microns (see section 1.2) at a concentration of 20% (see section 3). Mattson further teaches an active ingredient (e.g. DCP) with particle size as low as 90 microns (see Table I). Regarding the disclosed 20% of microcrystalline cellulose, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium

Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05.

The process of spray-drying mannitol recited in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Martani explains that the disclosed tablet is beneficial for patients who have difficulty swallowing tablets (*see* page 1, third full-paragraph).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a fast disintegrating tablet comprising mannitol, active agent, microcrystalline cellulose, sodium croscarmellose, and a lubricant, as taught by Martani. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a tablet because it is beneficial for patients who have difficulty swallowing tablets, as explained by Martani.

* * * * *

Response to Arguments

Applicant's arguments filed on 11 March 2010 have been fully considered but they are not persuasive.

Applicant argues that the claimed spray dried mannitol is distinct from the mannitol used in the Mattson reference. See remarks, page 7.

The instant specification states that PEARLITOL by Roquette is an example of spray-dried mannitol (see page 6, lines 7-9). Applicant states in the remarks that PEARLITOL is available in granulated form (see remarks, page 7). Applicant further acknowledges that Mattson teaches granulated mannitol at Section 1.1 on page 1 (see remarks, page 7). As such, examiner respectfully submits that the form of mannitol disclosed by Mattson meets the definition of spray-dried mannitol disclosed by the instant specification.

Applicant argues that Mattson does not disclose what proportion of the active ingredient particles are between 90 and 100 micrometers. See remarks, page 8.

"The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . .In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results. *See* MPEP 2144.05.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP § 716.02(d) - § 716.02(e). See In re Blondel, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and In re Fouche, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was found sufficient to rebut a prima facie case of obviousness. MPEP 716.02(b).

Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (differences in sedative and anticholinergic effects between prior art and claimed antidepressants were not unexpected). In In re Waymouth, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." Compare In re Wagner, 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967) (differences in properties cannot be disregarded on the ground they are differences in degree rather than in kind); Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) ("we generally consider a discussion of results in terms of differences in degree' as compared to differences in kind' . . . to have very little meaning in a relevant legal sense").

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615